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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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Certifier A. Corbin

New Animal Drugs for Use in Animal Feeds; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Phibro Animal Health, Inc. The supplemental NADAs provide for a 0-day preslaughter withdrawal time for use of oxytetracycline in cattle feed.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rt. 46 East, suite 401, Fairfield, NJ 07004, filed supplements to NADA 8-804 for TM-50, TM-50D, TM-100, and TM-100D (oxytetracycline) Type A medicated articles and NADA 95-143 for TERRAMYCIN 50, TERRAMYCIN 100, and TERRAMYCIN 200 (oxytetracycline) Type A medicated articles used for making medicated feeds for the treatment of various bacterial diseases of livestock. The supplemental NADAs provide for a 0-day withdrawal time prior to slaughter when Type C medicated feeds containing oxytetracycline are fed continuously to calves, beef cattle, and nonlactating dairy cattle at a dosage of 10 milligrams

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per pound of body weight for up to 14 days. The supplemental NADAs are approved as of March 12, 2004, and the regulations are amended in 21 CFR 558.450 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

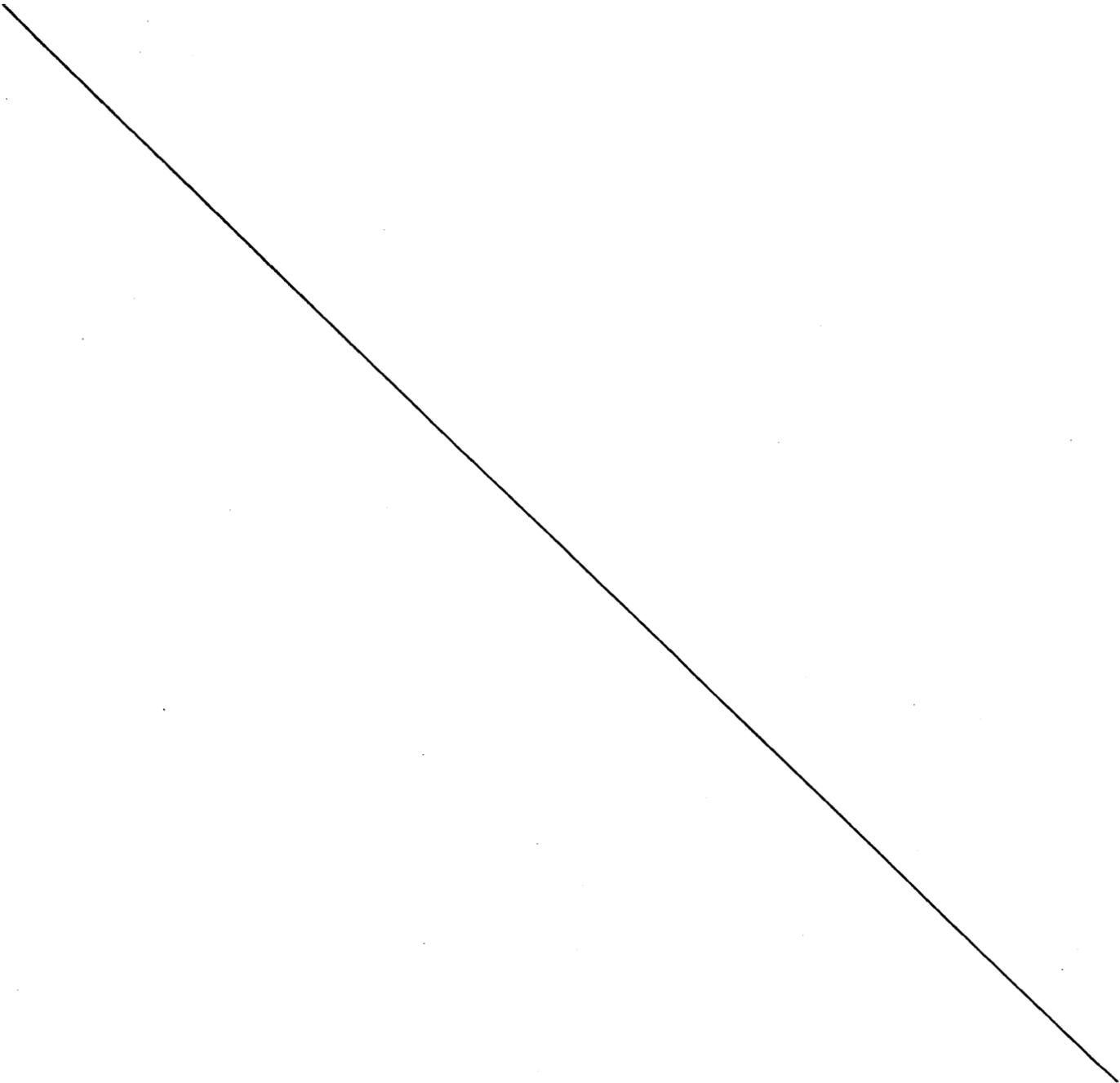
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.450 [Amended]

- 2. Section 558.450 *Oxytetracycline* is amended in the table in paragraph (d)(1)(ix) in entries 1 and 2 in the “Limitations” column by removing “withdraw 5 d before slaughter” and by adding in its place “for No. **053389**, withdraw 5 d before slaughter; for No. 066104, 0-day withdrawal”.



Dated: April 14, 2004
April 14, 2004.

Steven D. Vagin

Steven D. Vagin,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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